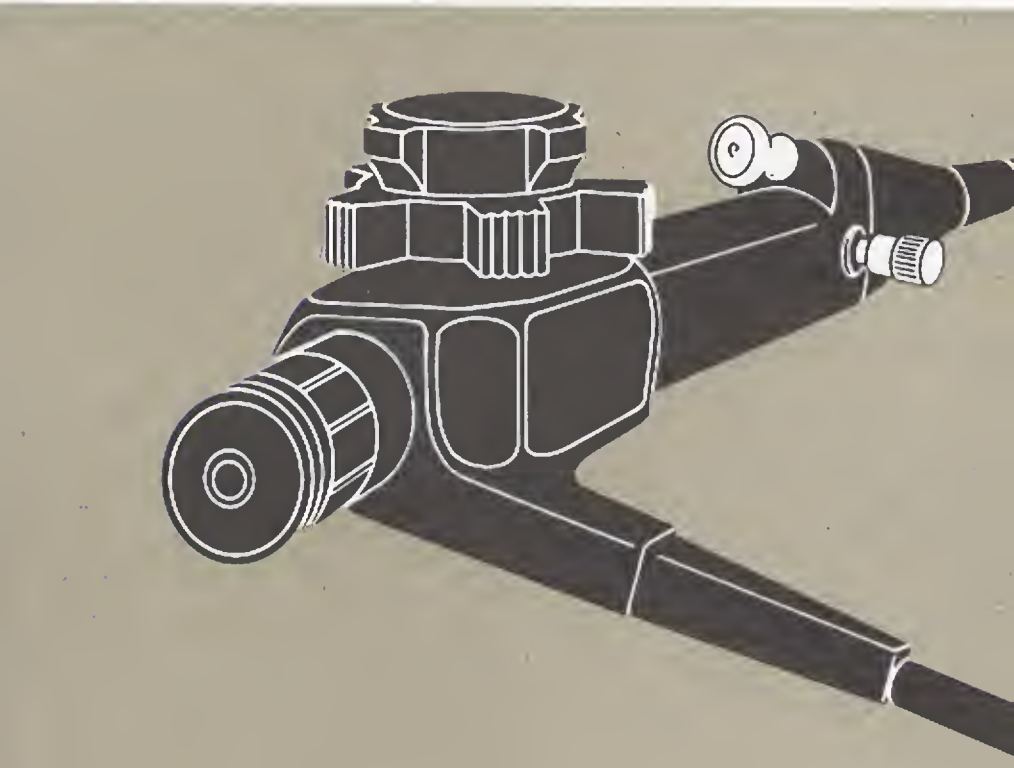
Welch Allyn

FX-100™ Flexible Sigmoidoscope

and LX-150™ Light Source Operating Instructions



Welch Allyn

Thank you for purchasing the Welch Allyn FX-100 Flexible Sigmoidoscope. The operating and maintenance instructions found in this manual should be followed to ensure many years of accurate and reliable service. Please read these instructions thoroughly before attempting to use your new FX-100 Flexible Sigmoidoscope.

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Warning

The user of the FX-100 Flexible Sigmoidoscope should be thoroughly trained in the medical procedures appropriate to the equipment. Furthermore, time should be taken to read and understand these instructions before performing any procedures. Instructions for other equipment used in conjunction with the flexible sigmoidoscope (e.g. electrosurgical generators, suction machines, snares, etc.) should also be read and understood. Failure to do so may result in injury to the patient and/or damage to the instrument.

While this manual describes the recommended protocol for inspecting and operating the equipment, it does not outline procedure techniques. Only physicians trained and versed in the procedure of flexible sigmoidoscopy should use this equipment.

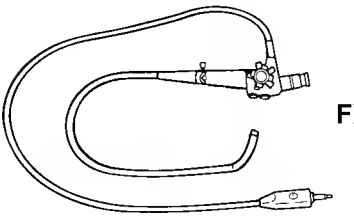
Specifications

Description	Specification
Working Length	65 cm
Insertion Tube Diameter	13.6 mm
Biopsy Channel Diameter	3.2 mm
Bending Section Deflection Range	180°Up/Down 160° Right/Left
Angle of View	100°
Depth of Field	3-100 mm
Inflation	Automatic
Water Feed	Manual/Automatic
Immersible	Yes

Components

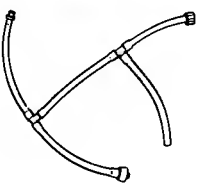
FX-100 Flexible Sigmoidoscope

#33900 Fiber Optic Sigmoidoscope Includes:



FX-100 Fiber optic sigmoidoscope

#33910 Cleaning brushes (2 ea.)

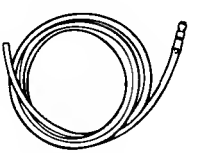


#33911 All channel irrigator

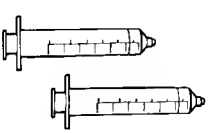
#33919 Air/water disinfection cap

#33930 Biopsy seals (10 each)

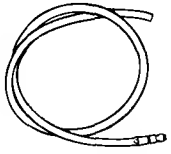
#33907 Manual irrigation tubing



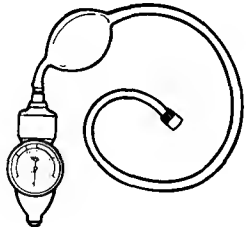
#33913 Suction tubing



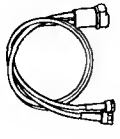
#33908 2 Each — 30 cc syringe



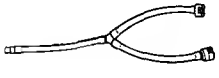
#33912 Biopsy cleanout adaptor



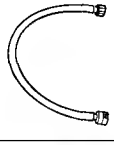
#33922 Leakage tester



#33906 Dual lumen air/water line



#33916 Air/water disinfection line

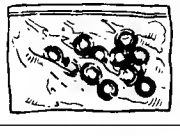


#33914 Blowout adaptor

#33918 Valve lubricant

#33924 Air/Water nozzle cleaning brush

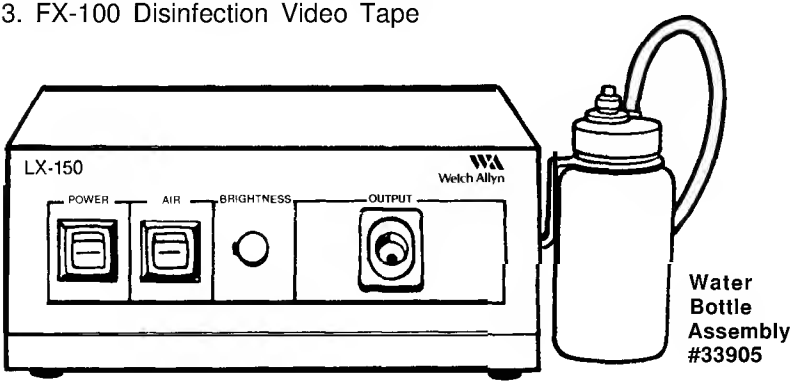
(Actual Size)



#33923 Air/water & suction valve "O" rings (12 per bag)

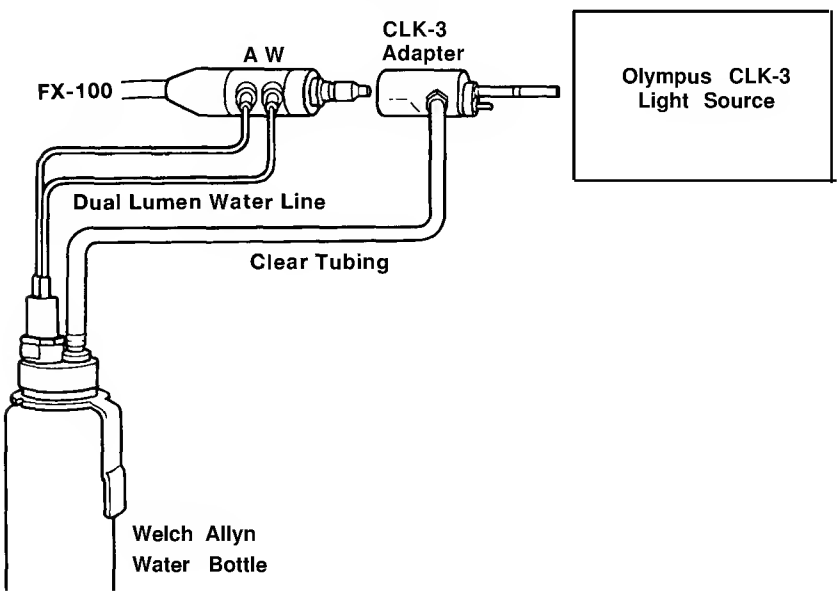
LX-150 Light Source

#45250 Light Source includes:
1. Light source – LX-150
2. Water bottle assembly – #33905
3. FX-100 Disinfection Video Tape



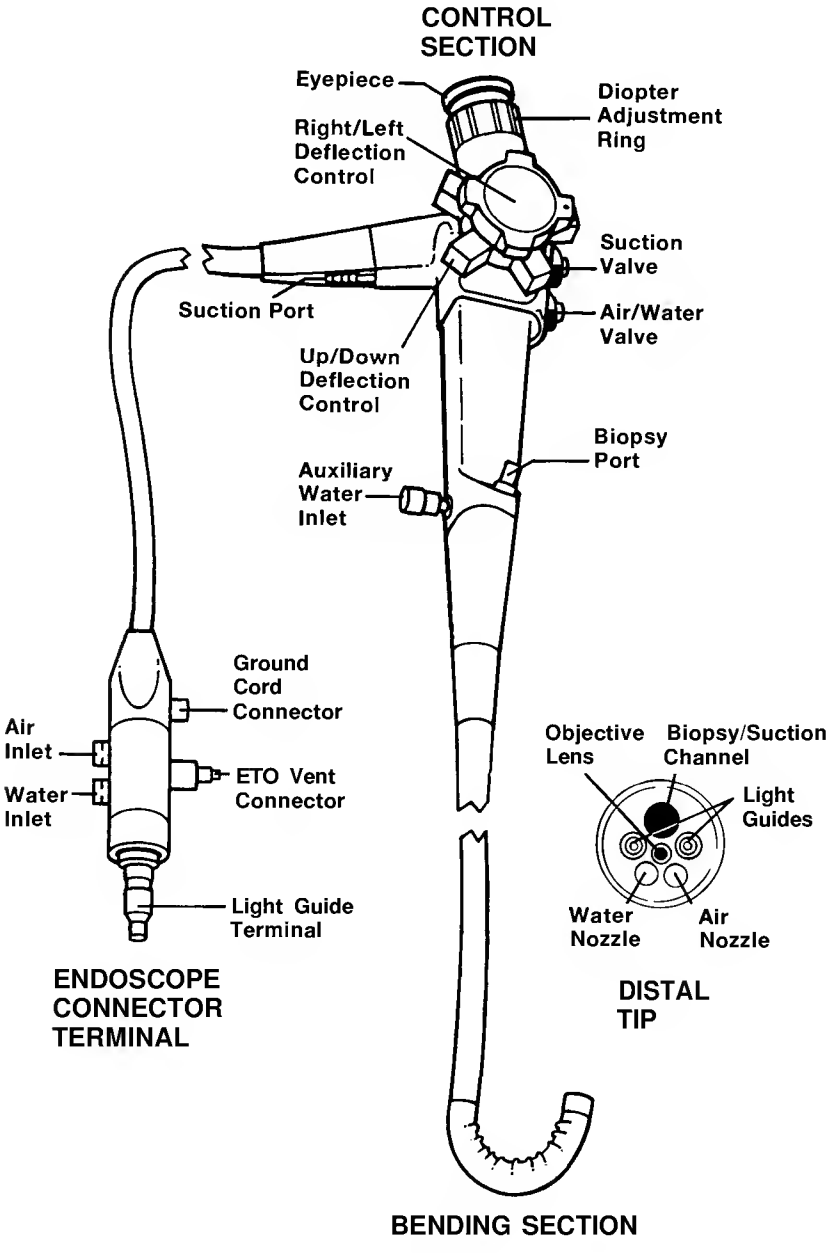
Adaptor

#45157 CLK-3 Adaptor (Olympus)
Allows the FX-100 to couple to an Olympus CLK-3 light source

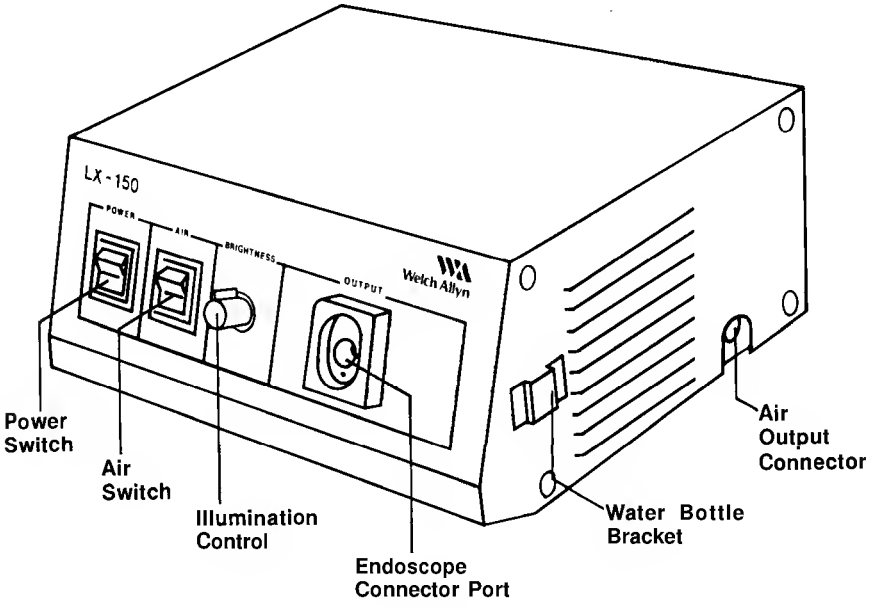


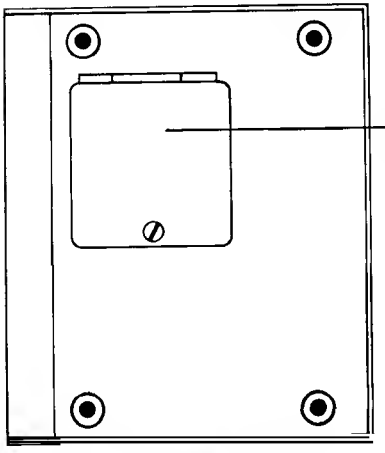
Nomenclature

Fiber Optic Sigmoidoscope

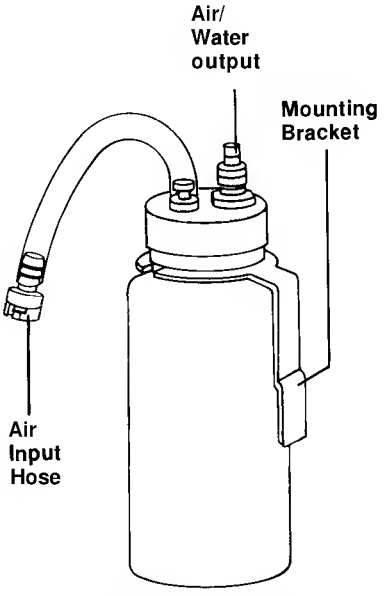


Light Source





BOTTOM VIEW



WATER BOTTLE

Prior to Initial Use

Before preparation or set up of the equipment, check all components received against list of components (see components section) to verify complete set. If parts are missing, please notify Welch Allyn. Review the nomenclature, setup, operation and cleaning/disinfection sections to become familiar with the equipment.

Specifically, inspect:

Fiber Optic Sigmoidoscope

- **Insertion tube —** for tears, cuts, dents, bubbles, bumps
- **Control section —** depress valves, test bending section deflection to assure smooth rotation of controls
- **Biopsy channel —** pass cleaning brush through biopsy/suction channel to verify smooth passage

Light Source

- **Cabinet —** for any dents, scratches or other abnormalities

System Setup

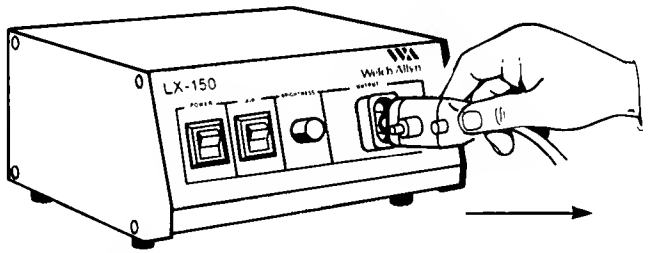
Light Source

1. Plug the light source into a properly grounded 110-120 volt AC outlet. Activate power and air switches to verify functionality of illumination and pump.
2. Fill water bottle approximately 3/4 full of clean tap water. Replace and tighten the cap and attach to water bottle bracket on the right side of light source.
3. Connect air input hose on water bottle to air output connector on right side of light source.

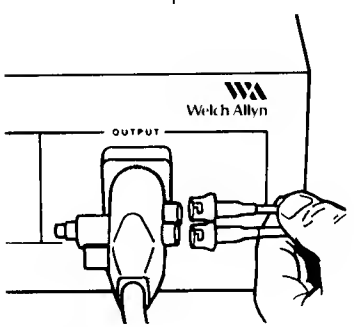
Fiber Optic Sigmoidoscope

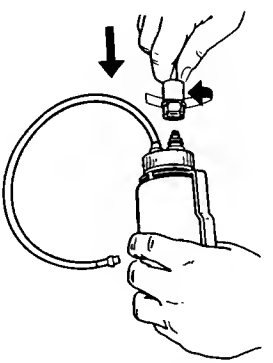
NOTE: Endoscope should be cleaned and disinfected prior to initial use, following the steps starting on page 24 and 35, or in the FX-100 cleaning and disinfection video tape.

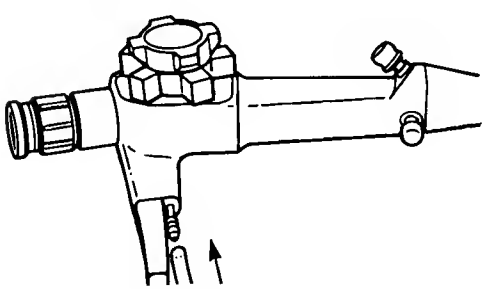
1. Plug endoscope connector terminal into endoscope connector port of light source. Push gently until it "snaps" into place.



2. Connect ends of dual lumen air/water line to the color coded air/water outputs on endoscope connector terminal (White = Water, Green = Air). Attach remaining end to water bottle. Mount 3/4 filled water bottle on light source bracket and couple remaining hose to air output connector.







3. Connect suction tube to suction port on control section. Attach remaining end to suction source receptacle.

4. Verify biopsy seal is seated in place over biopsy port opening.

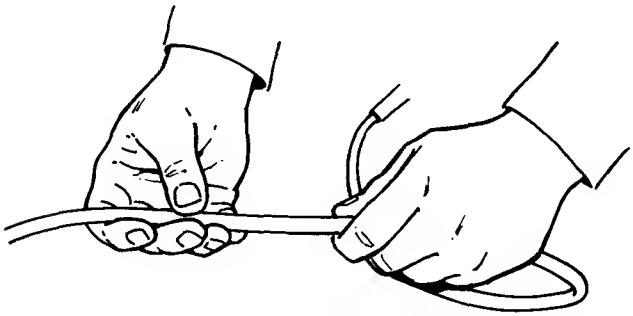
System Inspection

The following steps should be repeated prior to every procedure to verify that the system is working. If any problem is encountered, immediately consult the troubleshooting section of this manual or contact your local Welch Allyn distributor or representative for assistance.

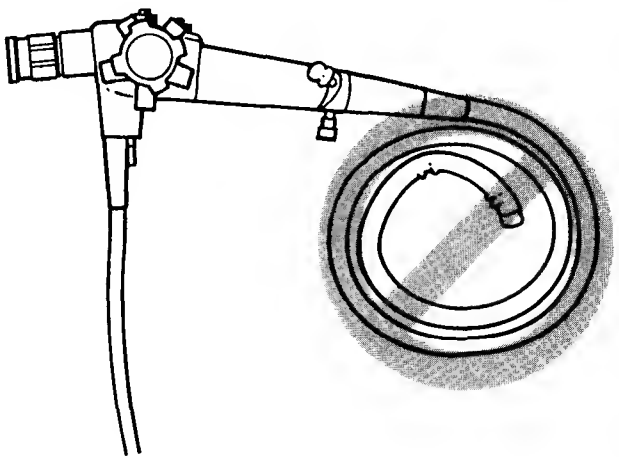
Physical Inspection:

Insertion Tube and Bending Section

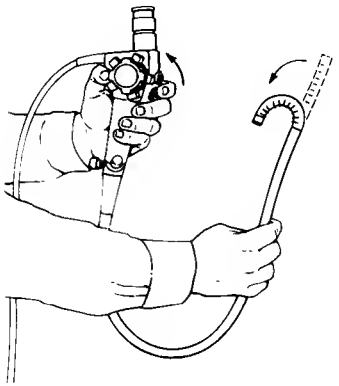
- Inspect the insertion tube for tears, cuts, dents, bubbles, bumps or other abnormalities on the surface.
- Run your fingers carefully over the entire length to check for protruding braid, internal looseness or other abnormalities.



CAUTION: Do not wind insertion tube into a tight radius. Serious damage to internal fibers could result. Proper storage procedures are outlined on page 50.

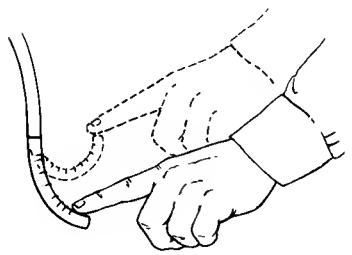


Deflection Controls



- Operate deflection controls slowly in all directions. Make sure that deflection is smooth and that no friction or grinding is present.

- **Up/down plane** — rotate the down deflection control knob to its limit in each direction. It should rotate without excess friction.



- **Right/left plane —** rotate the right/left deflection control knob to its limit in each direction. Unlike the up/down control, a slight resistance or "drag" should be apparent. This is a design of the scope that allows the bending section to remain in position without holding the control knob. The bending section should not lock into position. To verify this, deflect the control to maximum and release. The bending section should return to a straight or neutral position by applying gentle pressure with your index finger.

WARNING: If the resistance in the right/left deflection plane is higher than normal, DO NOT USE the instrument. Contact Welch Allyn Customer Service for assistance.

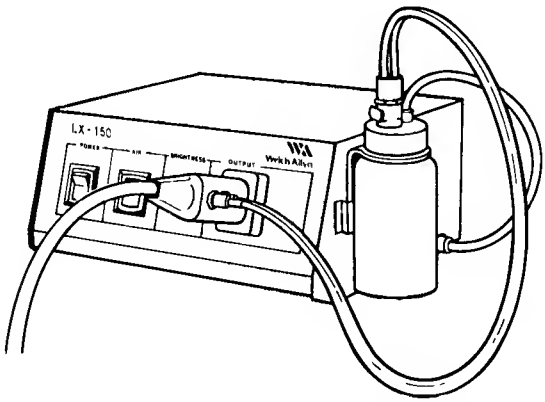
CAUTION: Do not deflect the bending section by hand. This applies excess force to the deflection mechanism and may result in failure.

Light Source

1. Activate "power" switch. This will start the lamp and cooling fan.

CAUTION: Do not look directly into the endoscope connector port when activating the light source.

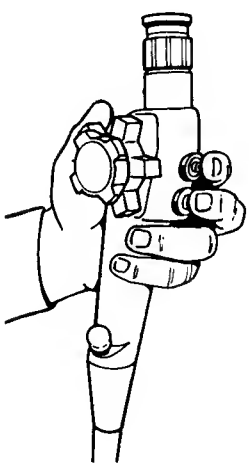
2. The output of the light source is then controlled by the illumination intensity control. Clockwise rotation will increase illumination output. Counter clockwise will decrease illumination.

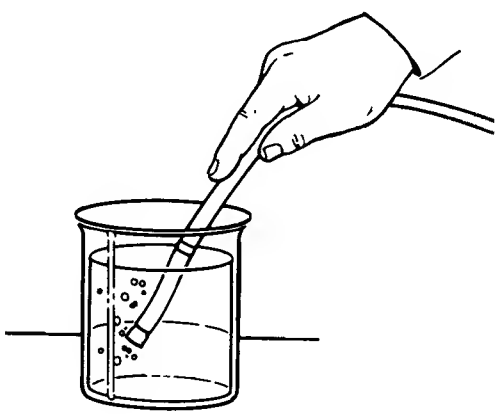


3. Activate "air" switch. This will start the internal insufflation pump.

Inspection of Air Feed

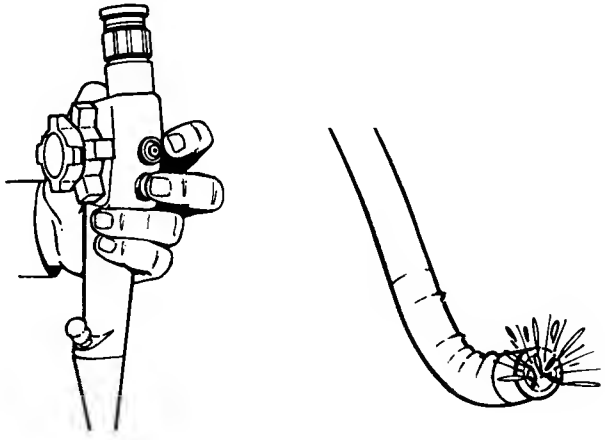
1. Place tip of bending section into clear water. Cover hole on top of air/water valve with finger tip. Do not depress valve. Air should flow freely through the instrument and water should bubble vigorously.
2. Remove finger — bubbling should end immediately.





Inspection of Water Feed

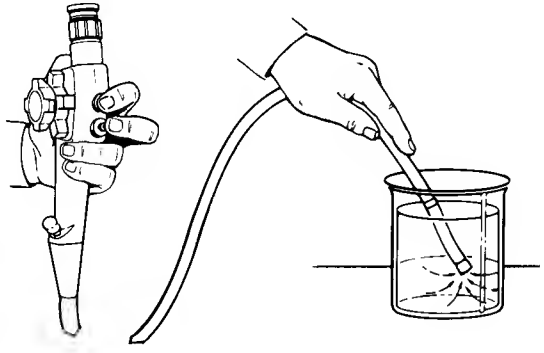
1. Depress air/water valve completely. Water should flow in a constant stream over objective lens and light guides.
2. Release valve — water flow should end immediately.



NOTE: Upon initial setup, depress and hold down valve for a few seconds for water to completely fill line in instrument.

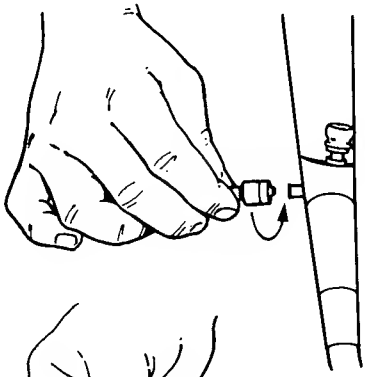
Inspection of Suction

1. Verify that suction tubing is attached and suction machine is on.
2. Immerse tip of bending section into clear water and completely depress suction valve.
3. Verify aspiration by viewing water flow into suction receptacle. Releasing valve should stop suction immediately.

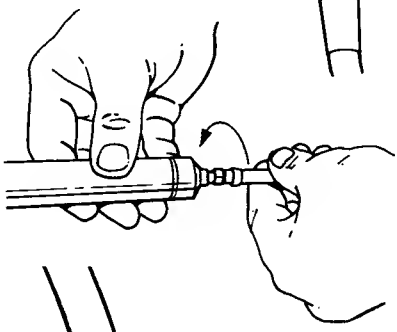


Inspection of Manual Water Feed

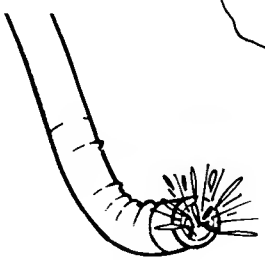
1. Connect manual irrigation tubing to auxiliary water inlet on endoscope.



2. Fill syringe with clean tap water and connect to remaining end.



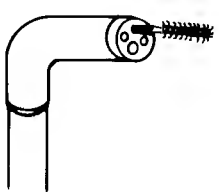
3. Feed water through inlet and verify that it exits from water nozzle over objective lens and light guides.



NOTE: If leak occurs at inlet, tighten connector. If leak continues, call Welch Allyn Customer Service.

Inspection of Biopsy/Suction Channel

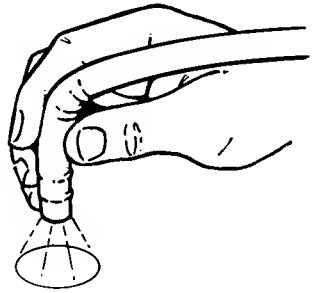
1. Deflect bending section 90° in "up" direction.
2. Pass cleaning brush or forceps through the biopsy channel to verify a clear pathway.
3. Repeat Steps "1 and 2" in three remaining directions.



NOTE: If resistance is encountered, DO NOT force. Contact Welch Allyn Customer Service.

Inspection of Light Guides and Optics

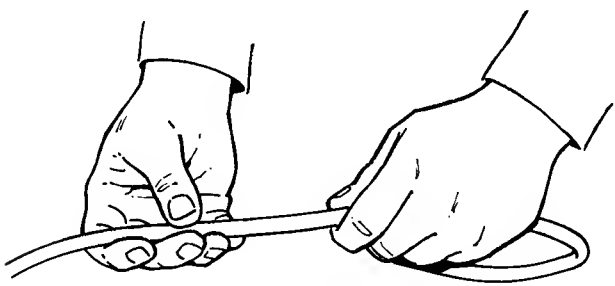
1. With lamp on, hold distal tip approximately 40 mm from any printed surface.



2. Verify light is being emitted from light guides.
3. Hold eyepiece to your eye and rotate diopter ring until print is in focus. Verity focus from 10-40 mm from surface.

Inspection of Umbilical Cord

Check the umbilical cord for cracks, dents, crushed and twisted areas.



2. Verify that the endoscope connector terminal's light guide terminal fitting is tight and does not move when moderate pressure is applied.

NOTE: Instrument should be cleaned, disinfected and sterilized prior to every use. (Follow steps starting on pages 22 and 47, or demonstrated in the FX-100 cleaning and disinfection video tape).

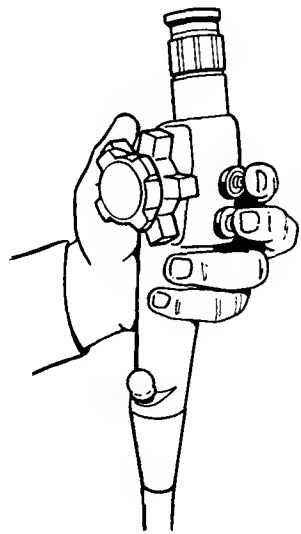
Procedure

The methods and techniques of flexible sigmoidoscopy are well defined and documented. Endoscopy training seminars and preceptorship programs are also in existence worldwide.

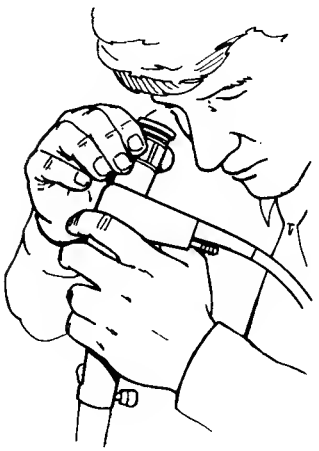
No attempt is made in this manual to outline the medical procedure or techniques of flexible sigmoidoscopy. The physician should always take care to understand the clinical background of each patient and the possible contraindications of the procedure.

Holding the Instrument

The control section is designed for the left hand. The "V" formed by the left thumb and index finger should be positioned beneath the area where the umbilical cord exits the control section. The suction and air/water valves are controlled by the index finger and middle finger respectively. The up/down deflection control is operated by the thumb. The right hand is used to advance and rotate (torque) the insertion tube. In some instances, it may be necessary to have an assistant hold the insertion tube while the right/left deflection control is rotated by the right hand.



Insertion/Operation:



Objective Lens Focusing

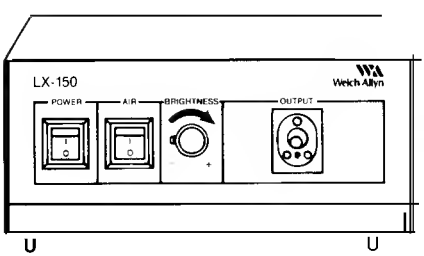
- Hold the distal tip 30-40 mm from a flat, printed surface.
- Rest eyepiece on cheek bone of right eye.
- Rotate the diopter ring until the characters are sharp and in focus.

Insertion

- Prior to insertion, the bending section and distal portion of the insertion tube should be lubricated with a **water soluble lubricant.** DO NOT cover the light guides or objective lens.
- DO NOT use lubricants that are petroleum based as these will deteriorate the rubber covering the bending section.

NOTE: Patient preparation should be adequate so that no fecal material is present, If prep is poor, discontinue immediately.

NOTE: If the image during insertion becomes red and out of focus (a "red out"), this is a sign that the tip is in contact with the mucosal wall. DO NOT ADVANCE FURTHER. Slowly withdraw the instrument and gently inflate the colon until lumen is visible.



Light Intensity Adjustment

- Once lumen is visible, adjust the light intensity control to desired setting.

NOTE: The distal tip of the sigmoidoscope may become warm, if in continuous operation with illumination set too high, and may damage mucosa. Use the lowest light setting possible.

Tip Deflection

- Slowly operate the deflection controls to guide the instrument through the lumen

CAUTION: If resistance is encountered, DO NOT force deflection controls. Doing so may damage the instrument and/or injure the patient.

CAUTION: DO NOT advance the instrument if lumen is not visible. Blind advancement could result in perforation.

WARNING: If during the procedure the deflection controls cease to function, terminate examination. Return both deflection controls to the neutral position, by rotating the deflection controls slowly until the "up" and "right" markings on the control knobs are in line with the eyepiece. Slowly withdraw the endoscope while viewing through the eyepiece. Do not operate controls.

Flushing Objective Lens

- Lubricant, mucous and fecal materials can cloud or fog the objective lens. The lens can be cleared by depressing the air/water valve.
- If a more forceful wash is required, attach the manual irrigation tubing to the auxiliary water inlet and flush with a syringe filled with clean tap water.
- Water drops retained on the lens can be removed by covering the hole on top of the air/water valve.

Suction

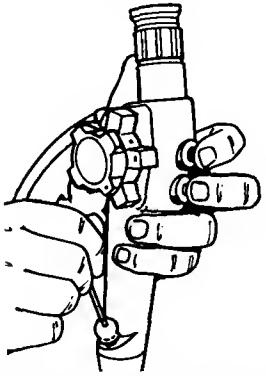
- Fluid, secretions, and liquid stool can be aspirated by depressing the suction valve.
- Aspiration will also remove excess air introduced during insufflation

CAUTION: Care should be taken to avoid sucking mucosa into the channel. This phenomena can result **in a "suction polyp" that can be mistaken for a lesion.**

Insufflation

- A collapsed lumen can be opened by insufflation. Cover air/water valve to inflate colon. Adequate insufflation can be maintained by insufflation and aspiration of air.

CAUTION: DO NOT overinflate the colon. This may cause severe patient discomfort as well as inhibit insertion.

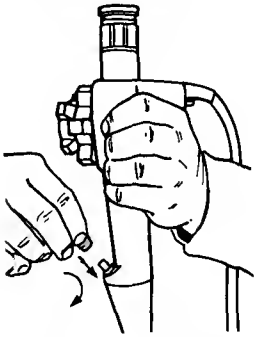


Biopsy Passage

- Biopsy forceps and accessories should be inserted through the biopsy seal and into the channel.
- The forcep should be advanced using short strokes, started by grasping the forcep sheath no more than 4 cm from the channel opening.

WARNING: If resistance is encountered during passage through the bending section, relax deflection angle until passage is smooth and easy. Wetting the forcep with water or a medical grade silicon lubricant will promote easier passage.

- If biopsy seal "spits" or leaks while instrument is in place, remove defective seal and replace.



NOTE: When replacing biopsy seal, rotate one full turn clockwise after pushing on luer-loc fitting to insure a proper seal.

NOTE: Always flush biopsy channel immediately after a procedure by aspirating clear water through the channel (see cleaning). This will assist passage of instruments in subsequent procedures.

Obtaining a Biopsy

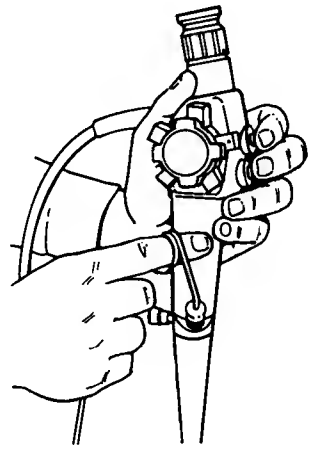
- Collect tissue sample by opening forcep and advancing open cups up against the mucosa. Close cups slowly until resistance is felt, and then hold. Gently pull back on forcep until small tissue sample is removed.

WARNING: DO NOT open forcep until biopsy cups are out of the biopsy channel and can be visualized. Doing so may damage biopsy channel.

CAUTION: DO NOT exert excess force when closing forcep. Such action may damage forcep.

- Always withdraw forcep with the cups in a closed position.

NOTE: If forcep fails to close during a procedure, close cups by winding the proximal portion of the forcep cable around your index finger. If forcep still does not close, withdraw cups as close as possible to the distal tip and slowly withdraw the instrument under direct visualization.

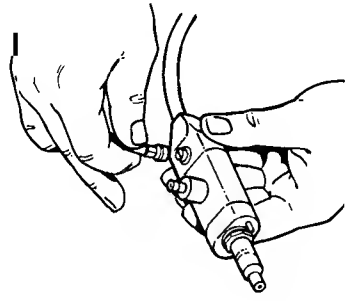


Electrosurgery

Warning:

Before attempting endoscopic electrosurgery, the operator should be thoroughly trained and versed in the technique and be knowledgeable of the risks associated with the procedure. There have been reported cases of explosion due to inadequate bowel preparation. Therefore, any preparation that does not evacuate and clean the bowel entirely, is a contraindication to this procedure. Medical experts agree that this procedure is extremely hazardous if performed with an enema prep only. However, if performing an electrosurgical procedure through the flexible sigmoidoscope, the S-cord should be attached to the sigmoidoscope and the remaining end to the chassis of the electrosurgical generator.

Electrosurgery Connections



- Remove safety cap from ground cord connector.
- Connect the S-cord's terminal nut to the ground cord connector on the endoscope connector terminal.
- Secure the other end to the chassis of the electrosurgical unit.
- To reduce the risk of electric shock, both physician and assistant should wear rubber gloves.
- DO NOT turn electrosurgical generator on until just prior to use.

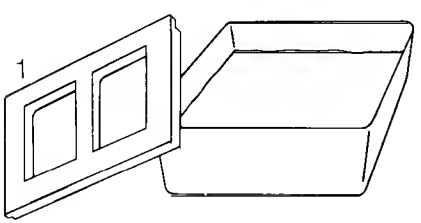
Cleaning and Disinfection

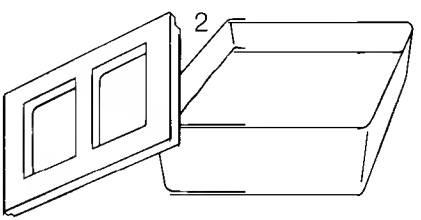
Endoscopic instruments should be cleaned immediately after each use. Endoscopes are delicate and will degrade if not cleaned promptly, due to the effects of digestive contents — blood, mucous, etc. The methods outlined on the following pages have been tested and verified to have no damaging effects. Therefore, these procedures should be adhered to.

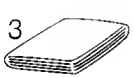
NOTE: Cleaning and Disinfection Program — The complete cleaning and disinfection process has been videotape recorded to assist you in learning the correct way to care for your instrument. The video tape and accompanying laminated guide is included with the light source in the top of the shipping box. If you did not purchase a light source and would like Welch Allyn to send you a video tape, please call Customer Service at 1-800-535-6663.

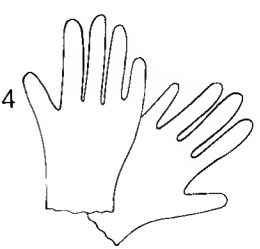
Supplies Needed (for cleaning and disinfection)

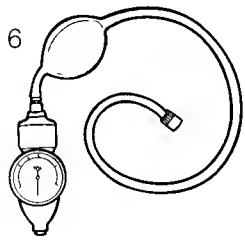
1. Large basin of water
2. Cleaning solution (soap solution)
3. Gauze pads
4. Disposable gloves
5. Cleaning brush*
6. Leakage tester*
7. Biopsy cleanout adaptor*
8. 2 Each — 30 cc syringe*
9. Air/water nozzle cleaning brush*
10. Blowout adaptor*
11. All channel irrigator*
12. Air/water disinfection line*
13. Air/water disinfection cap*
14. Isopropyl alcohol
15. Cotton Swabs
16. Suction tubing*
17. Suction machine
18. Valve lubricant*
19. Soft bristle brush







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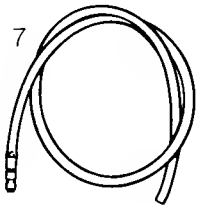
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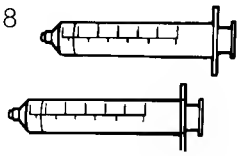
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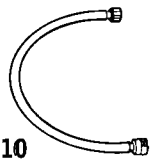
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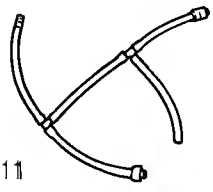
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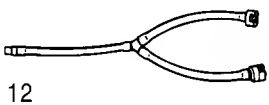
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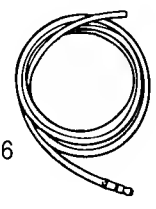
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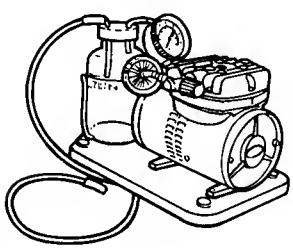
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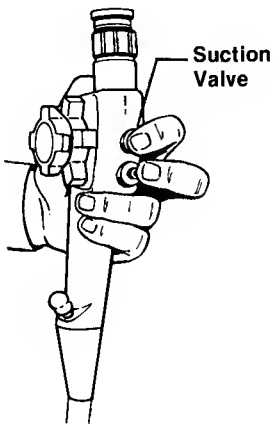
*This component is included with the FX-100 Sigmoidoscope

Cleaning

Immediately After Procedure...

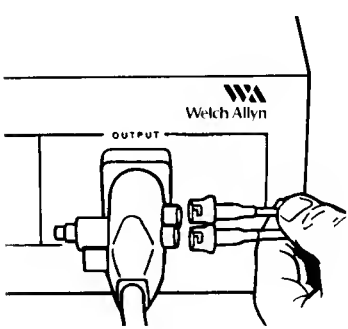
1. With instrument still coupled to suction machine, insert distal tip into clean water and depress suction valve.

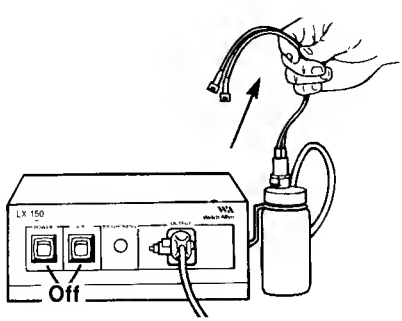
   Aspirate until water running through suction line is clear.
   Turn off suction device and disconnect suction line.



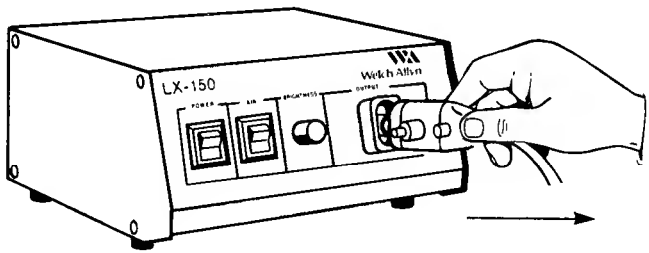
2. Turn off "air" and "power" switches on light source. Disconnect dual lumen air/water line from air and water inlets on endoscope connector terminal.

NOTE: After disconnecting, elevate air/water line above the top of the water bottle to drain any water in the line back into the bottle. If not performed, the siphon created by the water system under pressure will force the water through the open connectors. Tie the line in a loose knot on too of the water bottle to avoid any dripping.

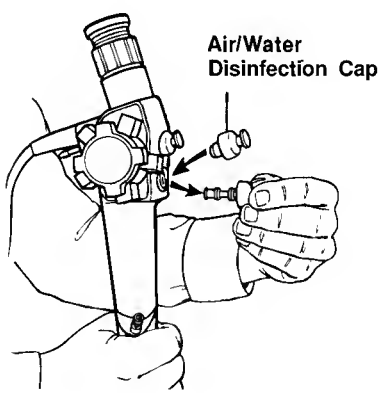


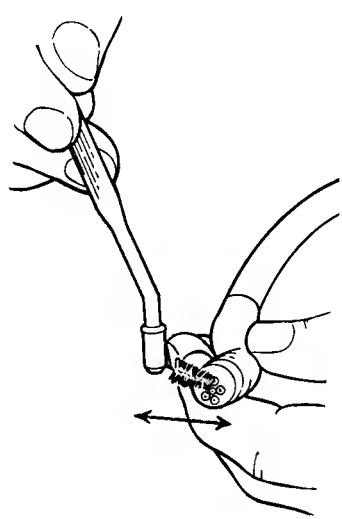


3. Remove the instrument from the light source by grasping the endoscope connector and pulling back gently.

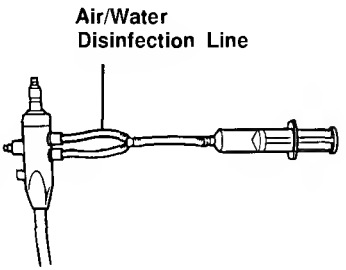


4. Place the insertion tube into soap solution and scrub the insertion tube lightly with a gauze pad dampened in soap solution.
5. Remove the air/water valve (identified by two blue rings on the top of the valve), grasp and pull up, place into soap solution. Replace the valve with the air/water disinfection cap. Gently brush the air and water nozzles in the distal tip with a soft brush to dislodge any debris. Take care not to push any debri back into the air and water lines.





6. Locate the air/water disinfection line and attach the side with two fittings to the air and water inlets on the endoscope connector terminal. Fill a 30 cc syringe with clean water and couple it to the remaining end. While holding down the air/water disinfection cap with a finger, inject water through the air/water lines until it sprays from both nozzles in the distal tip. Uncouple the syringe from the tubing.

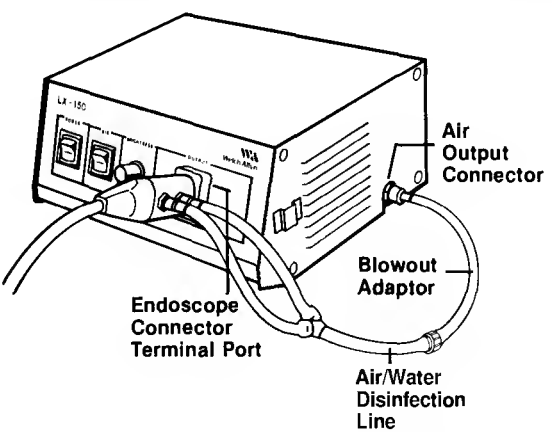


7 The next step is to purge the water that was just introduced into the air and water lines. This can be accomplished using one of the following two methods:

A) Refill the 30 cc syringe with air. Re-couple to the air/water disinfection line and inject air to purge the system. Repeat. Disconnect the syringe and air/water disinfection line.

OR

B) Couple the single end of the air/water disinfection line to the blowout adaptor. Re-seat the instrument's connector terminal into the connector port of the light box. Attach the free end of the blowout adaptor to the air output connector on the side of the light source. Activate light source "power" and "air" switches. Hold down the air/water disinfection cap to blow both the air and water lines dry. Continue for approximately 15 seconds. Turn the switches on the light source to the "off" position and disconnect all lines and the instrument from the light source.



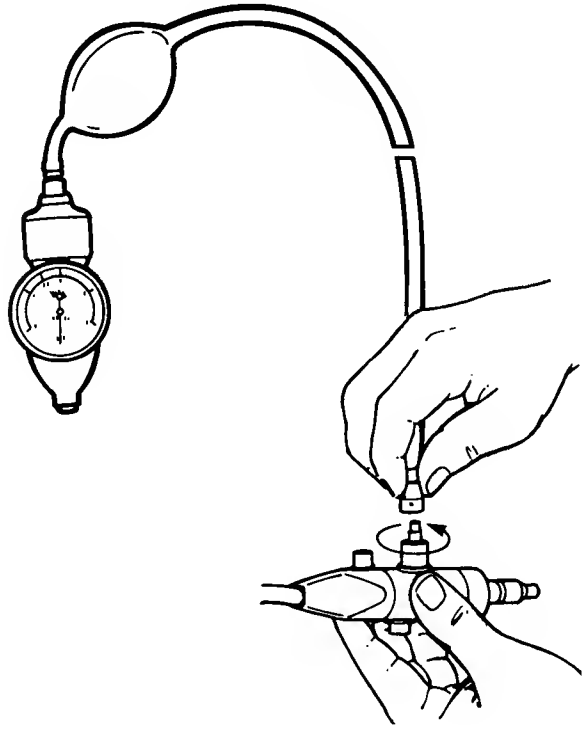
Steps A and B achieve the same results --- simply choose the step that you can best incorporate into your routine for cleaning.

8. **Perform Leak Test Procedure.** The leakage test allows for a simple two stage test of the watertight integrity of the instrument. Air pressure is introduced into the interior of the instrument by means of a hand pump. The instrument is then checked for pressure decay via a gauge and then visually.

Stage 1

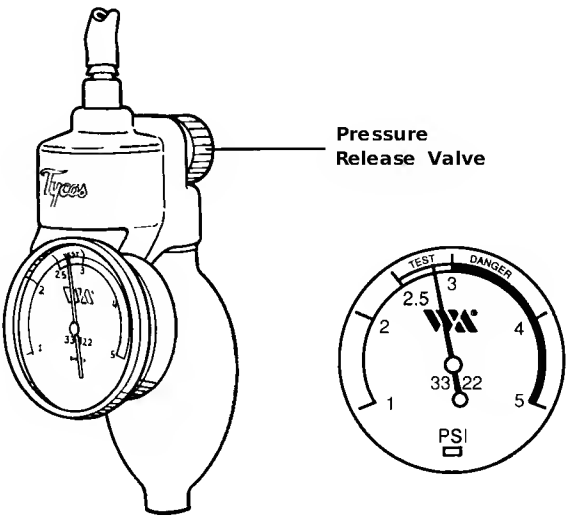
BEFORE IMMERSION, the instrument should be tested for any major loss of integrity in its watertight construction (example: major tear in the bending section).

A. Secure the Leakage Tester to the ETO vent connector on the instrument's endoscope connector terminal. The Leakage Tester connector and the ETO vent connector MUST be dry before securing. To properly connect, align air vent pin, depress and rotate clockwise.



B. Pressurize the inside of the instrument by pumping the hand bulb until the indicator needle on the gauge is within the "TEST" zone. DO NOT pressurize into the "DANGER" zone; doing so may result in serious damage to the instrument.

NOTE: Make sure that the pressure release valve on the back of the gauge is closed.



NOTE: The rubber covering the bending section will expand. This indicates an increase in internal pressure and is normal.

C. Observe the gauge indicator needle to determine if the indicator remains in the "TEST" zone. If the indicator drops out of the "TEST" zone rapidly, a major leak in the instrument is indicated.

NOTE: Be certain that the pressure release valve has been tightened.

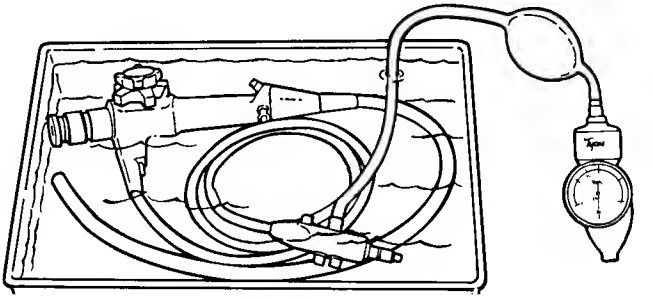
DO NOT proceed to Stage II Test, if the indicator needle does not remain in the "TEST" zone. Instead, contact Welch Allyn Customer Service.

Stage II

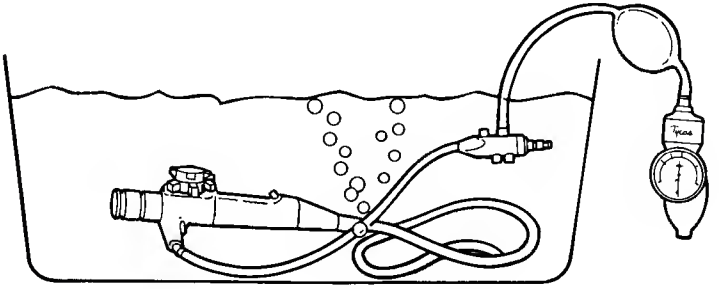
After determining the absence of any major leak in Stage I testing, the instrument may be immersed in clean water to test for loss of integrity in the watertight construction due to small pin hole leaks.

A. With the Leakage Tester securely attached to the instrument and the gauge indicator needle in the "TEST" zone, the entire instrument may be immersed in clean water.

NOTE: Only the Leakage Tester connector and a small portion of its tubing should be immersed. NEVER immerse the entire Leakage Tester.



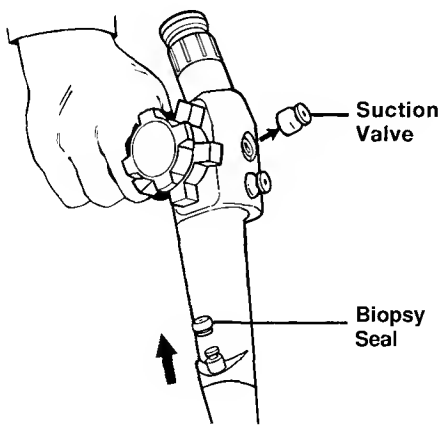
B. Observe the instrument carefully. A few bubbles may initially rise from recessed areas of the scope. This is normal. If a continuous stream of bubbles is observed from the same spot, a leak is indicated. Immediately remove the scope from the water. DO NOT attempt to use the instrument for a procedure. Clean and disinfect the instrument to the best of your ability without immersing it and call Welch Allyn Customer Service at 1-800-535-6663.



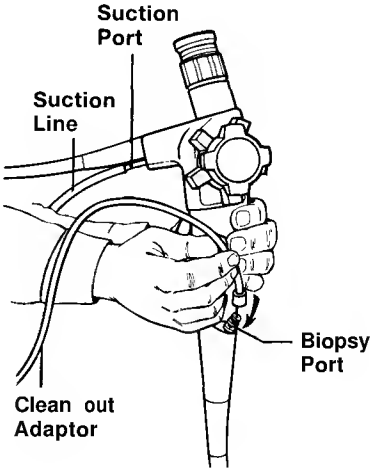
9. After removing the instrument from water, release the air pressure by opening the pressure release valve on the handle of the Leakage Tester. After the gauge indicates "ZERO", disconnect the Leakage Tester from the scope.

   NOTE: NEVER connect or disconnect the Leakage Tester under water. This will cause leakage of water into the instrument and Leakage Tester.

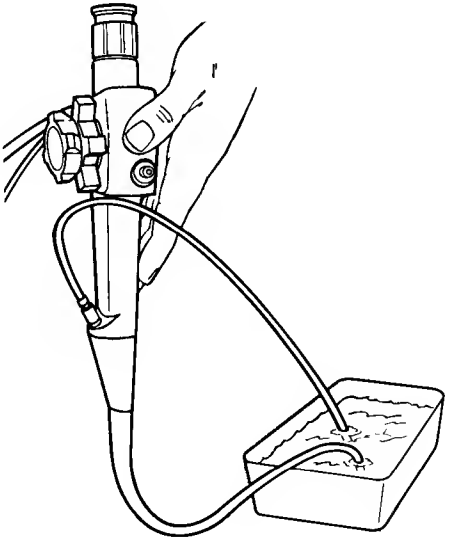
10. Remove suction valve (identified by two red rings on the top of the valve) and white biopsy seal by grasping and pulling upwards. Place them in soap solution to soak.



11. Attach suction line to suction port and biopsy cleanout adaptor to the open biopsy inlet.



12. Place the distal end of the instrument and the other end of the cleanout adaptor into the soap solution. Activate suction machine and cover the open suction valve well with a finger to aspirate soap solution through the biopsy/suction channel in all directions. Continue for about 10 seconds. Turn off suction machine and disconnect all tubing.

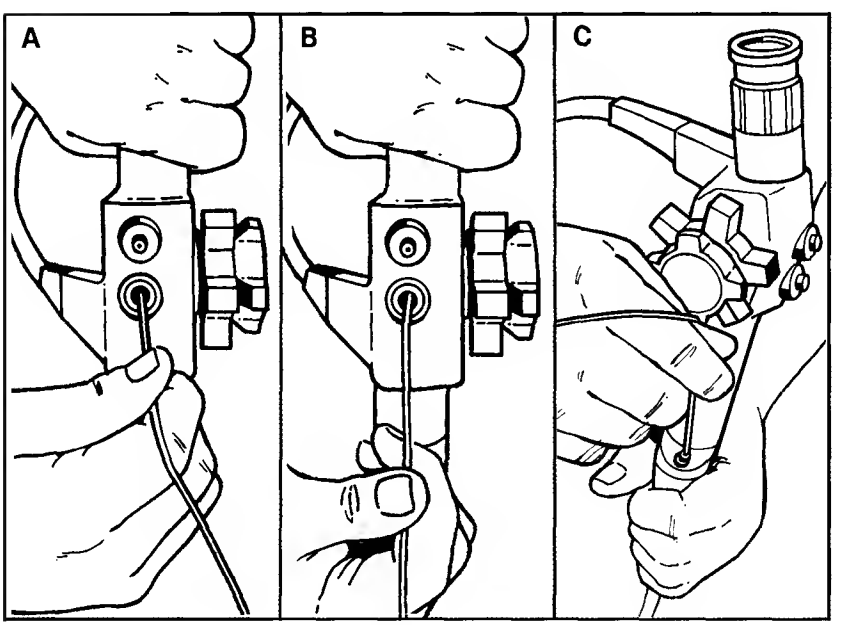


13. Insert a cleaning brush through biopsy/suction pathways in three directions:

    a. Insert cleaning brush into the suction valve well perpendicular to the top of the control section. Advance the brush until it emerges from the suction port. Remove any debris from the brush with a gauze pad, and remove the brush by pulling back through the instrument.

    b. Insert the cleaning brush into the open biopsy port and advance for about 6 to 10 inches. Remove the brush and clean any solid debris off the tip using a gauze pad.

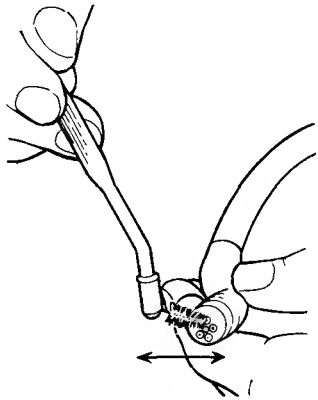
    c. Insert brush back into suction valve well, angle it 45 degrees toward the distal tip and advance until it exits the biopsy/ suction channel opening in the distal tip. Remove all debris from the tip of the brush with a gauze pad soaked in soap solution and pull back to remove.



NOTE: If brush will not pass-DO NOT force. Disinfect instrument to the best of your ability and contact Welch Allyn Customer Service at 1-800-535-6663.

WARNING: **Forcing brush through can damage the suction channel.**

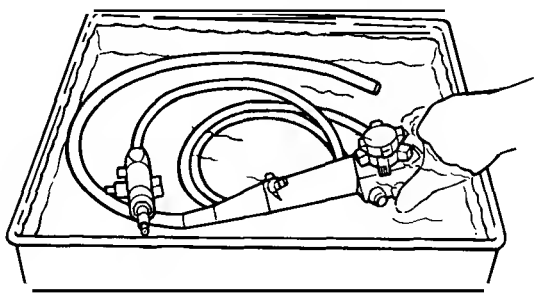
14. Place the entire instrument into soap solution and gently brush all external surfaces with a soft bristled brush. Brush the air/water inlet nozzles with the air/water nozzle brush across the nozzle openings, take care not to push any debris back into the air and water line. Gently scrub the valves and biopsy seal with a soft bristle brush.



15. Remove instrument from soap solution and reattach suction line. Place instrument, valves and biopsy seal into clean water. Rinse thoroughly.

NOTE: Rinse valves thoroughly as residue can cause valve to stick.

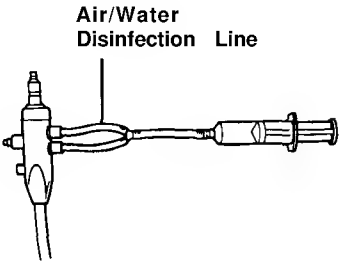
16. Turn on suction machine. With instrument immersed in clean water, cover open suction valve well with finger to aspirate clean water through the channel to rinse. Continue for approximately 15 seconds.



17. Lift entire instrument out of basin of water and, with the suction valve well still covered, aspirate air through biopsy/suction line for 60 seconds to dry channel.

18. Disconnect suction line, dry exterior of instrument thoroughly. Dry the valves and biopsy seal and set aside.

19. Reattach the air/water disinfection line to the air and water inlets on the instrument's connector terminal.



20. The next step is identical to step #7 and it's purpose is to thoroughly dry the lines. This can be accomplished using one of the following two methods:

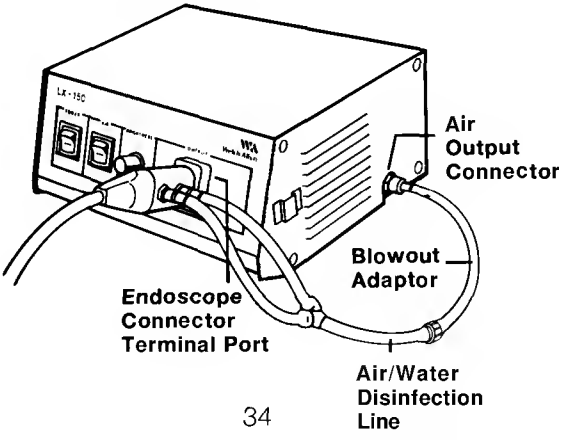
A) Refill the 30 cc syringe with air. Re-couple to the air/water disinfection line and inject air to purge the system. Repeat. Disconnect the syringe and air/water disinfection line.

OR

B) Couple the single end of the air/water disinfection line to the blow-out adaptor. Re-seat the instrument's connector terminal into the connector port of the light box. Attach the free end of the blowout adaptor to the air output connector on the side of the light source. Activate light source "power" and "air" switches. Hold down the air/water disinfection cap to blow both the air and water lines dry. Continue for approximately 15 seconds. Turn the switches on the light source to the "off" position and disconnect all lines and the instrument from the light source.

Steps A and B achieve the same results — simply choose the step that you can best incorporate into your routine for cleaning.

The instrument is ready for sterilization/disinfection.



Disinfection

The Welch Allyn flexible sigmoidoscope is manufactured from a variety of special materials which optimize instrument performance, but may not withstand some disinfection solutions and methods.

- Prior to disinfection, flexible endoscopes should be thoroughly cleaned and dried following the methods previously defined. Incomplete or improper cleaning will decrease the effectiveness of solution exposure.
- Welch Allyn cannot recommend a disinfection solution on the basis of germicidal effectiveness.

WARNING: All instruments and accessories must be thoroughly rinsed after exposure to disinfection solutions. This removes all toxic residue and will prevent patient irritation and instrument degradation.

Solution exposure times for disinfection should be verified with solution manufacturer.

The materials listed below are considered safe for use with the Welch Allyn flexible sigmoidoscope if used according to manufacturer's instructions for disinfection and in accordance with the following methodology.

These solutions are extremely aggressive, and failure to follow the disinfection cycles precisely, including initial cleaning and final rinsing, may result in shortening instrument life.

Recommended Cold Disinfecting Solutions

Glutaraldehyde (2.0% only)

Banicide	Wavicide-01
Metricide	Zorbicide
Cidex	

WARNING: DO NOT use solutions that are oil based or contain a surfactant (such as Cidex 7 or Cidex Plus). Additionally, bleach solutions will permanently damage metal components of the instrument.

NOTE: To inquire about compatibility of the flexible sigmoidoscope with disinfection solutions not listed, please call Welch Allyn customer service.

Disinfection Tray

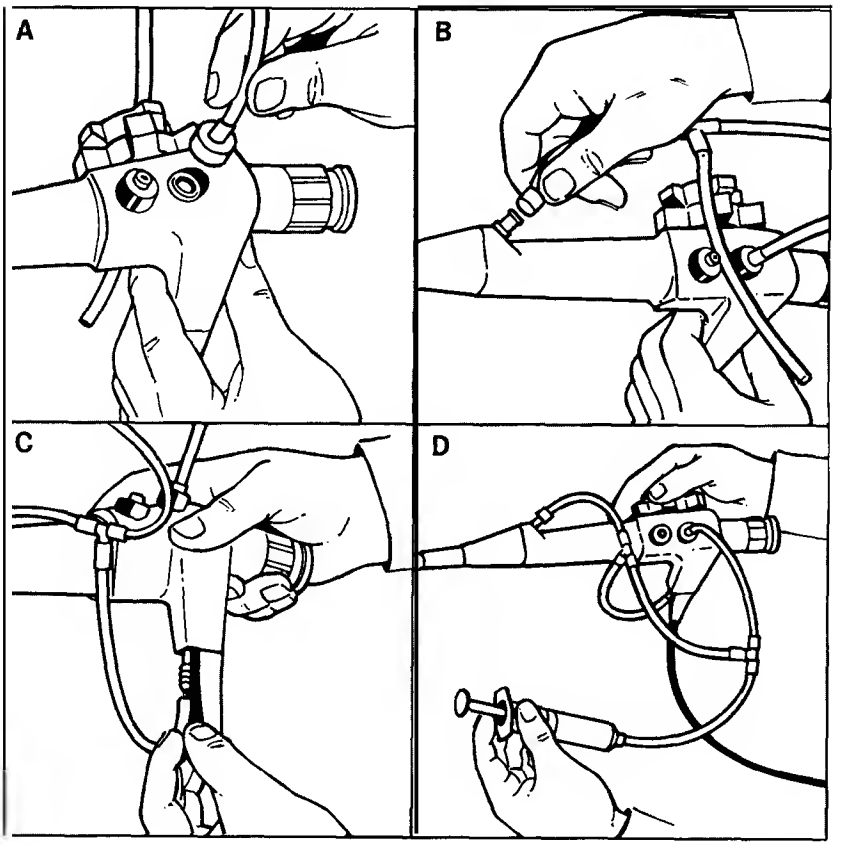
1. Fill the disinfection tray's clear tube with disinfectant to the black indicator dot on the top of the tube.
2. Fill a small covered container with additional disinfection solution and place the suction and air/water valves and biopsy seal into the container to soak.

NOTE: Air/water disinfection cap is still attached to the instrument,

3. Connect the all channel irrigator.

   A) Seat the black rubber suction valve well adaptor into the open suction valve well. Push down to snap the connector into place.

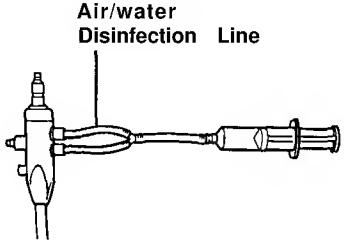
   B) Connect the silver luer-lock to the open biopsy port.



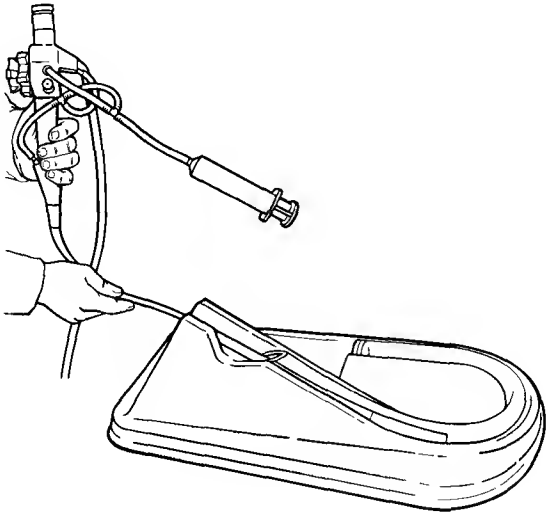
   C) Push free tubing onto the suction port.

   D) Connect a 30 cc syringe to the luer-lock fitting on the all channel irrigator.

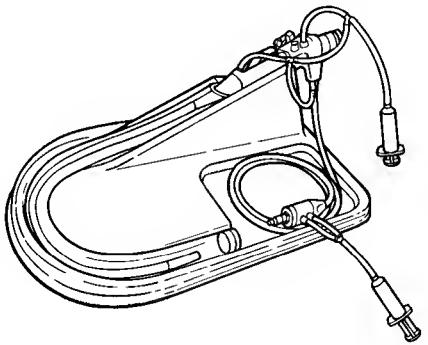
4. Connect the air/water disinfection line to the inlets on the endoscope connector terminal. Fill a 30 cc syringe with disinfectant from the covered container and connect the syringe to the end of the tubing.



5. Slide insertion tube into the tray's tube filled with disinfection solution and position the instrument's control section securely in the space provided on the tray.



6. Carefully wind the umbilical cord and place in the provided space on the tray. The attached syringes and tubing can hang over the side.

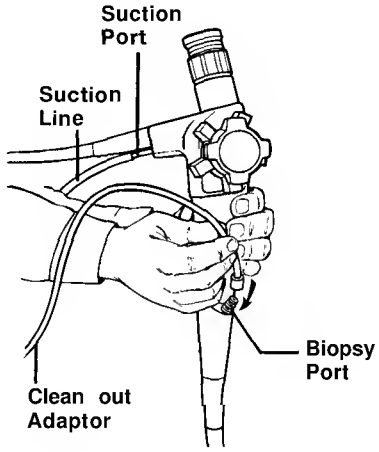


7. Pull back on the plunger of the empty syringe (connected to the all channel irrigator) to aspirate disinfectant into the instrument's biopsy/suction channel. Continue until the syringe is half full (15 cc). Leave the syringe connected and partially filled for the duration of the soak cycle (usually 15-20 minutes, refer to solution manufacturer's recommended time).
8. Hold down on the air/water disinfection cap and depress plunger of the syringe connected to the air/water disinfection line. Continue until fluid exits from the nozzles in the distal tip (i.e., until bubbling from tip stops, or the syringe is half full). Leave syringe connected for duration of soak cycle (usually 15-20 minutes, refer to the manufacturer's recommended time).
9. After soaking for the disinfectant solution manufacturer's recommended time, depress the plunger on the syringe connected to the all channel irrigator to expel solution.
10. Remove the syringe coupled to the air/water disinfection line and inject the remaining solution into the small covered container.
11. To purge all remaining solution, remove both syringes, fill them with air, reconnect, and one at a time, inject air into the channels.

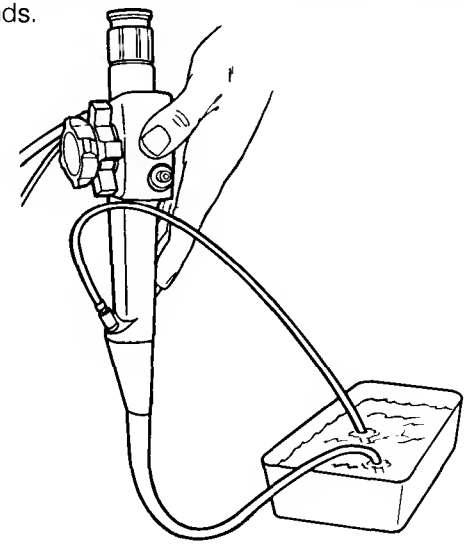
NOTE: Remember to hold down the air/water disinfection cap when injecting with the syringe coupled to the air/water disinfection line.

12. Detach the all channel irrigator and remove the instrument from the tray.

13. Place the insertion tube into a basin of clear water. Attach suction line to the suction port and the biopsy cleanout adaptor to the open biopsy port.



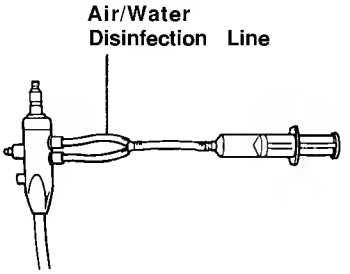
14. Place the suction and air/water valves and biopsy seal into the basin of clean water to rinse.
15. With distal tip of the instrument and free end of the cleanout adaptor under water, activate the suction machine and cover the open suction valve well with your finger to aspirate water through the entire biopsy/suction channel to rinse. Continue for approximately 10-15 seconds.



16. Disconnect syringe attached to the air/water disinfection line, fill with clean water, reattach to tubing, and inject water to rinse the air and water lines. Repeat this 2-3 times to thoroughly rinse the channels.

17. The next step's purpose is to thoroughly dry the lines. This can be accomplished using one of the following two methods:

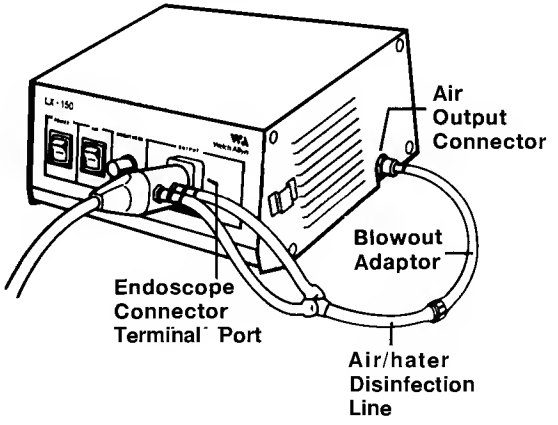
A) Refill the 30 cc syringe with air. Re-couple to the air/water disinfection line and inject air to purge the system. Repeat. Disconnect the syringe and air/water disinfection line.



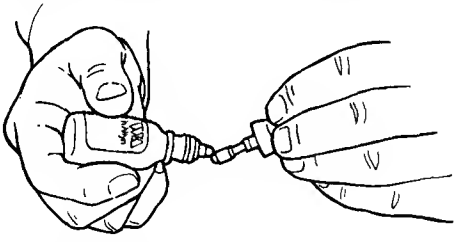
OR

B) Couple the single end of the air/water disinfection line to the blowout adaptor. Reseat the instrument's connector terminal into the connector port of the light box. Attach the free end of the blowout adaptor to the air output connector on the side of the light source. Activate light source "power" and "air" switches. Hold down the air/water disinfection cap to blow both the air and water lines dry. Continue for approximately 15 seconds. Turn the switches on the light source to the "off" position and disconnect all lines and the instrument from the light source.

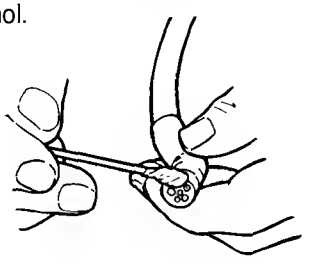
Steps A and B achieve the same results — simply choose the step that you can best incorporate into your routine for cleaning.



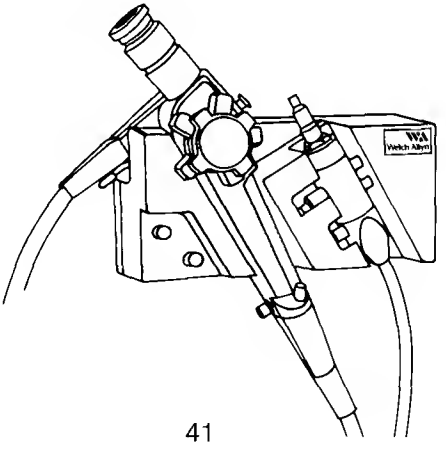
18. Disconnect the air/water disinfection line and biopsy cleanout adaptor
19. Wipe off the exterior of the instrument with a gauze pad moistened in clean water.
20. Lift the insertion tube out the basin. Cover the open suction valve well and aspirate air through the channel to dry.
21 .Turn off the suction machine, disconnect the suction line and dry the instrument's exterior.
22. Remove the valves and biopsy seal from the water and dry.
23. Apply a thin coat of valve lubricant to the valve's "O" rings and reseat them in the open valve wells. Reseat the biopsy seal.



24. Wipe off exterior of instrument with a gauze pad moistened in isopropyl alcohol. Clean distal lens with cotton swab dipped in isopropyl alcohol.



25. Hang scope with insertion tube straight to air dry.

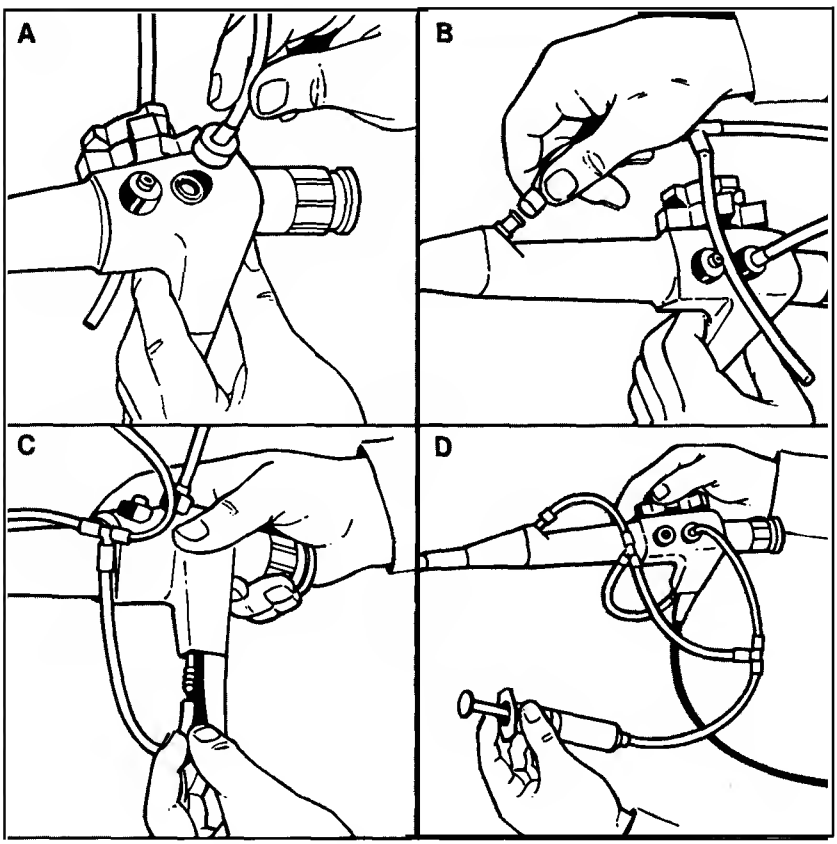


Disinfection - Immersion

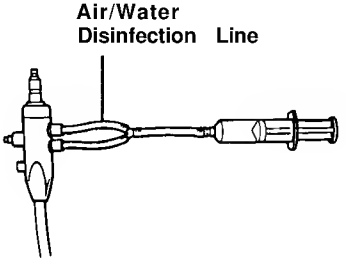
1. Fill covered basin with disinfectant to a level that will allow the entire instrument to be immersed in solution.
2. Place the air/water and suction valves and biopsy seal into solution to soak.

NOTE: Air/water disinfection cap is still seated in the air/water valve well.

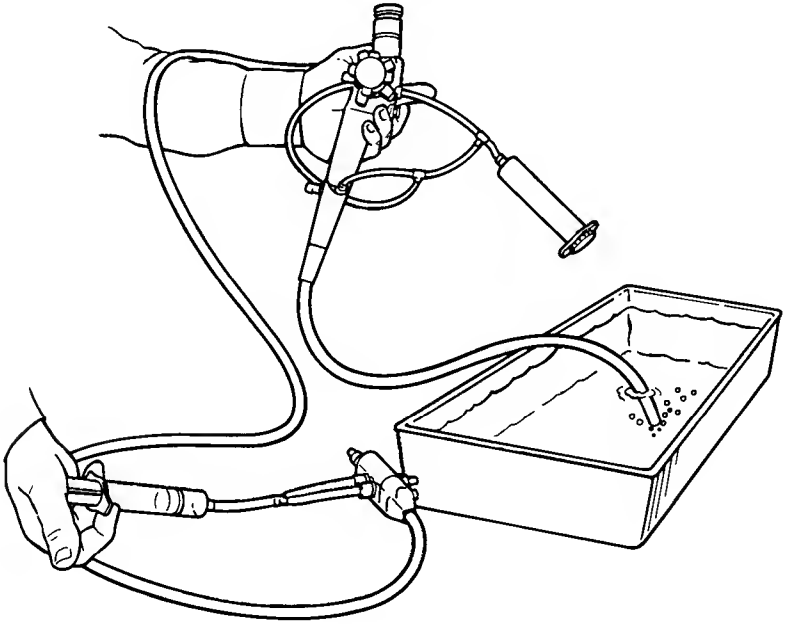
3. Connect the all channel irrigator.
   A) Seat the black rubber suction valve well adaptor into the open suction valve well.
   B) Connect the silver luer-lock to the open biopsy port.
   C) Push end of remaining free tubing onto the suction port,
   D) Connect a 30 cc syringe to the luer-lock fitting in the all channel irrigator



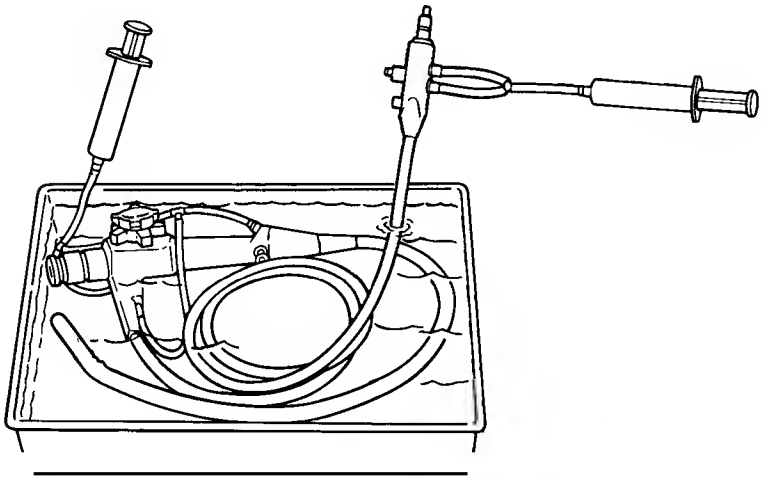
4. Connect the air/water disinfection line to the air and water inlets on the endoscope connector terminal. Fill a 30 cc syringe with disinfectant and connect to the remaining end of the line.



5. Place the insertion tube and distal tip into the disinfection solution while holding down the air/water disinfection cap, and depress the plunger of the syringe connected to the air/water disinfection line. Continue until the bubbles emerging from the air and water nozzles (distal tip) stop (usually 15 cc of solution).



6. Immerse the entire instrument in the disinfectant, with the exception of the syringes coupled to the all channel irrigator and the air/water disinfection line.



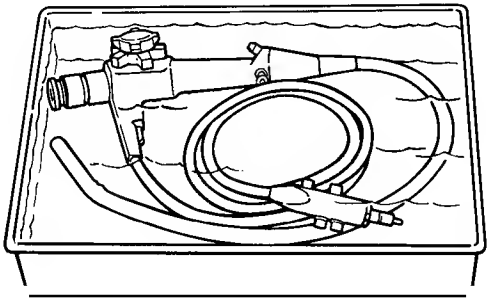
7. Draw back on the plunger of the syringe connected to the all channel irrigator until all lines of the irrigator are filled with solution (usually until syringe is half full).
8. Allow the instrument to soak in the disinfection solution for the manufacturer's recommended time (usually around 15-20 minutes).
9. After the soaking, depress the plungers of both syringes to purge remaining disinfectant. Remove both syringes and fill with air, reconnect. Depress the plungers, one at a time, to force air through the channels to purge the disinfectant. Repeat until clear.

NOTE: Remember to hold down the air/water disinfection cap when injecting with the syringe coupled to the air/water disinfection line.

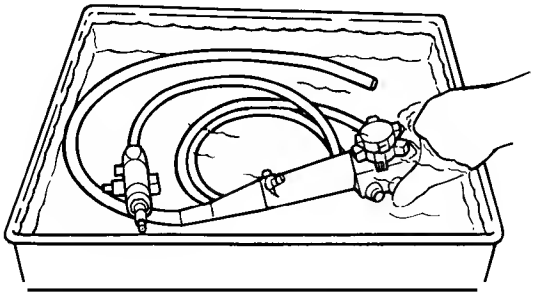
10. Remove the instrument from the disinfectant and detach the all channel irrigator.
11. Attach suction line to suction port and place instrument into a basin of clean water.

rinse the air and water lines, disconnect the syringe coupled to the air/water disinfection line. Fill with water, reattach, and while holding down the air/water disinfection cap, depress the plunger to inject water into the lines. Repeat 2-3 times.

13. Remove the syringe and air/water disinfection line and place the endoscope connector tubing into the basin to rinse.

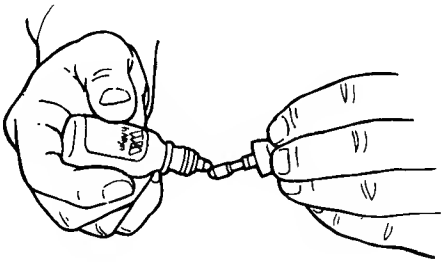


14. Place air/water suction valves and biopsy seal into the water to rinse.
15. Activate suction machine (suction line attached to suction port) and while the instrument is underwater, cover open suction valve well to aspirate water through the line to rinse. Continue for around 15 seconds.

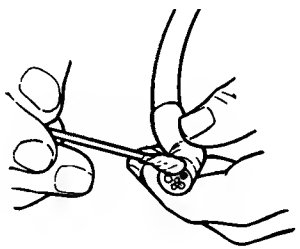


16. Wipe down exterior of instrument in clean water to rinse off any residual solution.
17. Lift the entire instrument out of the water and cover the open valve well with a finger to aspirate air through to dry the channel.
18. Turn off suction machine, disconnect the suction line, and dry the exterior of the instrument.

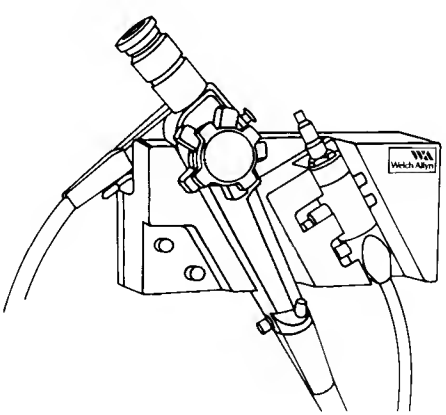
19. Lift the air/water and suction valves and biopsy seal from the water and dry.
20. Apply a thin coating of valve lubricant to the valve's "0" rings and reseat them in the open valve wells.



21. Wipe off exterior of instrument with a gauze pad moistened in isopropyl alcohol. Clean distal lens with cotton swab dipped in isopropyl alcohol.



22. Hang instrument with the insertion tube straight to dry.



Sterilization

Thorough mechanical cleaning and drying of the flexible sigmoidoscope are prerequisites to sterilization. If gas sterilization is required, the instrument should be sterilized following the methodologies outlined below:

NOTE: DO NOT steam autoclave the instrument. Doing so will result in severe damage.

Procedure

1. Remove suction, air/water valves, biopsy seal prior to exposure.
2. Attach the ETO vent cap (accessory) to the instrument.
3. DO NOT exceed 130°F or 10 psi.
4. Remove vent cap prior to next procedure.

NOTE: Gas exposure not to exceed 4 hours. Aeration time at room temperature is 7 days.

Troubleshooting Chart

Symptom	Possible Cause	Solution
Image is not clear.	Eyepiece not adjusted to user's eyesight.	Turn focus adjusting ring (diopter ring) until fiber pattern is in sharp focus.
	Distal objective obscured.	Rinse lens by injecting water through auxiliary water inlet.
	Lenses dirty.	Remove scope and clean distal objective and eyepiece with cotton swab and alcohol.
	Water damage to lens.	Return scope to Welch Allyn Service for evaluation/repair.
Inadequate suction.	Suction valve blocked.	Remove valve, clean valve and housing with a cleaning brush. Lubricate "O" rings with valve lubricant and replace.
	Biopsy seal is worn.	Replace biopsy seal.
	Suction channel blocked.	Call Welch Allyn Service Department for instructions.
	Suction pump not on or tubing disconnected.	Verify good connection between suction pump and scope. Turn pump on.
No insufflation.	Air pump not turned on.	Turn air pump on. Test scope for air flow.
	Air tubing not connected or pinched.	Verify that the dual lumen air/water lines are securely attached. Verify that water bottle input connector is coupled to light source.
	Air nozzle blocked.	Soak tip of scope in warm soapy water for 2-3 minutes. Gently brush with air/water nozzle cleaning brush. Connect dual lumen disinfection line. Gently inject warm water through air/water lines while cycling air valve. If nozzle remains blocked, contact Welch Allyn Customer Service.

Symptom	Possible Cause	Solution
No Insufflation. (cont'd.)	Water bottle cap not secured tightly.	Tighten cap.
Cannot irrigate.	Water bottle empty.	Fill water bottle.
	Water bottle cap not secured tightly.	Tighten cap.
Suction valve sticks.	Dirty valve stem.	Remove valve; clean valve and housing with cotton swab and alcohol; lubricate "O"rings with valve lubricant and replace.
Biopsy seal "spitting" or leaking.	Biopsy seal is worn.	Replace biopsy seal.
Insufficient articulation of tip.	Loose articulation knob.	Return scope to Welch Allyn for adjustment.
	Degree of articulation is less than specified.	Return scope to Welch Allyn for adjustment.
Inadequate illumination.	Illuminator not turned on.	Turn illuminator on and adjust light to appropriate intensity.
	Damage to light transmitting fibers.	Return scope to Welch Allyn for evaluation/repair.
Illuminator not working.	Not plugged into electrical outlet.	Plug illuminator into 120 volt grounded outlet.
	Lamp is burned out.	Replace lamp according to instructions.
	Fuse is blown.	Call Welch Allyn Service Department.

Maintenance and Storage

Maintenance:

Suction and Air/Water Valves

- Both suction and air/water valves should be inspected weekly. To remove, pull up on ring around valve stem to remove from its well.
- Clean each valve well with a succession of pipe cleaners until last cleaner is clean and dry (DO NOT use cotton tipped applicators).

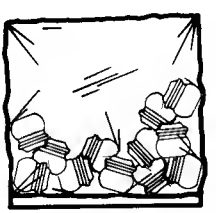
Air/Water and Suction Valves

1. Inspect valve stem.
2. Look closely at "O" rings.
3. If cracked or worn, replace.
4. To remove "O" rings, grasp with tweezer and remove. Roll new "O" rings into place over base of valve stem.

NOTE: Remove top "O" ring first before those at the base of the valve stem.

5. Lubricate valves by reapplying a light coat of silicone lubricant to "O" rings.

Biopsy Seals



To Seat: Push seal onto luer-lock fitting and rotate one full turn, clockwise.

To Remove: Pull seal while rotating counterclockwise.

To Flush Channel: Remove seal and connect syringe directly to luer-lock fitting.

Disinfection/Sterilization: Seal is compatible with all glutaraldehyde products and alcohol.

NOTE: To ease insertion of instruments, silicon or a water soluble lubricant can be injected into the chamber directly behind top opening. This will ease entry of instrument into and through biopsy channel.

Lens Cleaning

Moisten cotton-tipped applicator with 70% isopropyl alcohol. Clean debris from objective lens and light guides.

NOTE: DO NOT use abrasive materials to clean lens. Doing so could scratch and permanently damage optics system.

Storage

- Flexible sigmoidoscope should be stored with insertion tube and umbilical cord as straight as possible. If coiling is necessary, insertion tube and umbilical cord should not be wound in more than one loop.
- Flexible sigmoidoscope should not be stored in areas exposed to temperature extremes or high humidity. Storage area should be dry and clean.

Other manufacturers' accessories should be stored per their recommendations.

Service

Customer Service
Telephone Assistance:
1-800-535-6663

For repairs on the FX-100, ship to:
Welch Allyn Repair Department
4341 State Street Road
Skaneateles Falls, NY 13153

Welch Allyn, Inc.
4341 State Street Road
P.O. Box 220
Skaneateles Falls, NY 13153-0220
Telephone: (315) 685-4560
1 (800) 535-6663

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